DRAFT STATUTORY INSTRUMENTS

# 2022 No.

# The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022

**Transitional and saving provisions**

**19.**—(1) In any case where, prior to the coming into force of these Regulations, the licensing authority has issued an EAMS scientific opinion (under the pre-existing non-statutory arrangements) in respect of a medicinal product, the amendments to the Human Medicines Regulations 2012 made by these Regulations do not apply in respect of the sale or supply of, or the pharmacovigilance arrangements for, that product.

(2) Paragraph (1) ceases to apply in respect of the sale or supply of, or the pharmacovigilance arrangements for, that product once that EAMS scientific opinion is renewed (which the licensing authority may bring forward) or it ceases to have effect.

(3) Consent as mentioned in regulation 167H of the Human Medicines Regulations 2012 may be consent obtained prior to these Regulations coming into force.